



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,534	03/12/2004	Long Sheng Yu	76982-Z/JPW/JSW	7819
23432	7590	10/12/2011	EXAMINER	
COOPER & DUNHAM, LLP			ALTER, ALYSSA MARGO	
30 Rockefeller Plaza				
20th Floor				
NEW YORK, NY 10112				
			ART UNIT	PAPER NUMBER
			3762	
			MAIL DATE	DELIVERY MODE
			10/12/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/799,534	YU ET AL.	
	Examiner	Art Unit	
	Alyssa M. Alter	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1,3-6,8-10,12 and 14-17 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1,3-6,8-10,12 and 14-17 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 12 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 9, 2011 has been entered.

Response to Arguments

2. Applicant's arguments, see page 8, filed June 21, 2011, with respect to the rejection(s) of claim 12 under 35 U.S.C. 103 (a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made over Jassawalla et al. (US 6,001,056) in view of Poirier (US 4,086,665).

3. Applicant's arguments with respect to claims 1, 3-6, 8-10 and 14-17 has been considered but is moot in view of the new ground(s) of rejection, necessitated by amendment, in view of Poirier (US 4,086,665) and Jassawalla et al. (US 6,001,056) in view of Poirier (US 4,086,665).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3762

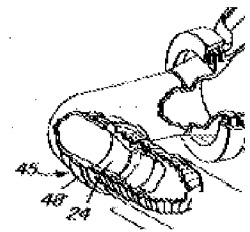
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Poirier (US 4,086,665). Poirier discloses a pump (depicted in figure 3 as 66), an inflow tube protruding from the pump portion (depicted in figure 3 as inlet connector 10), an adapter sleeve (curved section 76 in figure 3) extending from the inflow tube and forming an extended inflow tube with a greater length and a gripping member (inlet tube 78) having an opening and being configured to receive the extended inflow tube. As to the “gripping member”, the examiner considers the threads of the inlet tube 78 (see the cutaway of figure 3) to be the “gripping” portion of the “gripping member” that couples to the exterior surface of the extended inflow tube.

6. As to claim 3, as depicted in figure 3, the sewing ring (suture ring 80) is attached to the exterior of the gripping member.

7. As to claim 8, the inflow tube (inlet connect 10) included a bend end (adjacent to coupling 48). A replica of the bent portion of the inflow tube for figure 3 is included at right.



8. As to claims 9-10, the inflow tube (inlet connector 10) engages with the threaded end connector 36 of the adapter sleeve (curved section 76). The connection between the inflow tube and the threaded adapter can be seen in figure 1. In order to connect the inflow tube with the adapter sleeve, the inflow tube is necessarily rotatable in order to engage the threads of the inflow tube (retainer 38 and tube 14) with the threads of the end connector. Furthermore, the examiner considers the retainer 38 of the inflow tube to

Art Unit: 3762

be the "extendable end" that extends to engage with the end connector 36 of the gripping member.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 4, 6 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poirier (US 4,086,665). Poirier discloses the employment of biologically compatible titanium (col. 2, lines 38-39) but does not explicitly disclose the adapter sleeve is a smooth cylinder of titanium. Poirier discloses the device substantially as claimed except for the adapter sleeve being titanium or ceramic material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the material used for the adapter sleeve, since such a modification of the material would provide the predictable results of providing sufficient structure while maintaining in-vivo biocompatibility. Furthermore, it has been held to be within the general skill of a worker in the art to select a known material on the basis of

Art Unit: 3762

its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416 (See MPEP 2144.07)

12. Additionally, as to claims 15-16, Poirier discloses the device substantially as claimed but does not disclose the inclusion of gripping pins having gripping pads. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include gripping pins with gripping pads to ensure that the connection between the two components be maintained even in the event that the threaded connection becomes "stripped" (i.e. the threaded connection no longer creates a reliable connection) during attachment.

13. Claims 1, 3-6, 8-10, 12 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jassawalla et al. (US 6,001,056) in view of Poirier (US 4,086,665). Jassawalla et al. discloses a ventricular assist device with a pump (pumping portion 14 depicted in figures 1 and 2), an inflow tube (valved segment 22 in figures 1 and 2), adapter sleeve (flexible segment 26, depicted in figures 1-2, as well as figures 4-5). The inflow tube and the adapter sleeve together form the extended inflow tube. The adapter sleeve has a coupler fitting (coupling 182 in figure 4) for mating with the inflow tube (col. 5, lines 25-38). Jasswalla et al. additionally discloses stitch(es) 196 and 194 to couple the sewing ring to the exterior surface of the extended inflow tube (see figure 5).

14. Poirier discloses a threaded coupling between the extended inflow tube, inlet 10, and the inlet tube 76 that includes the suture ring 80. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the connection between the inflow tube and the sewing ring (stiches) of Jasswalla et al. for

Art Unit: 3762

the threaded connection between the inflow tube and the suture ring of Poirier in order to provide the predictable results of enabling a reliable and secure coupling that will be properly aligned and less dependent on the skill of the surgeon (i.e. in making appropriately placed and secure stitches).

15. As to claim 3, the ventricle assist device includes a sewing ring (depicted as 166 in figures 4-5). As depicted in figure 1, the cannula body (186 in figure 5) is inserted into the ventricular apex of the heart. Furthermore, since the gripping member (stitches) attach the exterior of the extended inflow tube to the sewing ring and the sewing ring is used to engage the ventricle of the heart, the sewing ring is "configured to attach said gripping members to a ventricular apex of a heart".

16. As to claim 5, Jassawalla et al. discloses a reinforcement cage (112 and 164 in figures 3 and 5 respectively) with the adapter sleeve. As such, the examiner considers the adapter sleeve to include the reinforcement cage. The reinforcement cage includes ribs 116 bridges 118 and axial spaces 120. Therefore, the axial spaces, or grooves, form perforations on the adapter sleeve that "separate the adapter sleeve".

17. As to claims 4 and 6, the modified Jassawalla et al. discloses the device substantially as claimed except for the adapter sleeve being titanium or ceramic material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the material used for the adapter sleeve, since such a modification of the material would provide the predictable results of providing sufficient structure while maintaining in-vivo biocompatibility. Furthermore, it has been held to be within the general skill of a worker in the art to select a known material on the basis of

its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416 (See MPEP 2144.07)

18. As to claim 8, the modified Jassawalla et al. discloses the claimed invention except for the inflow tube including the bent end. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the inflow tube to include the bent end instead of the pump, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70 (see MPEP 2144.04) Furthermore, such a modification would not alter the circulation of the blood but merely relocates the bent end from the pump to the end of the inflow tube that engages with the pump.

19. As to claim 9, the examiner considers the inflow tube of Jasswalla et al. to have an “extendable end” since one of the ends is configured to be attached to the adapter and thus extended. Thus, since the adapter is added to the inflow tube, the inflow tube includes an extendable end.

20. As to claim 10, the modified Jassawalla et al. teaches a threaded attachment between the extended inflow tube and the sewing ring (as seen in Porier figure 1). In order to connect the threaded extended inflow tube with the threaded component possessing the suture ring, the inflow tube is necessarily rotatable in order to engage the threads of the inflow tube with the threads of the suturing ring component.

21. Alternatively, the modified Jassawalla et al. discloses the claimed invention except for the inflow tube including a rotatable end. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the inflow

Art Unit: 3762

tube to include the rotatable end instead of the adapter sleeve, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70 (see MPEP 2144.04). Furthermore, such a modification would not substantially alter the engagement of the inflow tube and the adapter but merely changes which component has the coupler fitting.

22. As to claim 12, Jassawalla et al. discloses the reinforcement cage, which is attached to the adapter sleeve, permits the adapter sleeve to extend and contract (col. 6, lines 4-14). Therefore, the examiner considers the reinforcement cage to be the “adjustable attachment member configured to attach to the adapter sleeve” (as stated above in reference to claim 14). Therefore, the modified Jassawalla et al., as applied to claim 4 above, discloses an adapter sleeve (segment 26) made of titanium with an attached adjustable attachment member (reinforcement cage 122).

23. As to claim 14, Jassawalla et al. discloses a reinforcement cage (112 and 164 in figures 3 and 5 respectively). “The reinforcement cage 112 includes a plurality of circumferentially formed ribs 116 joined at periodic locations by bridges 118. Although not shown well in FIG. 3, the bridges 118 are circumferentially offset from each other from rib-to-rib to enable the reinforcement cage 112 to be axially extended (this is better seen in the conduit segment of the present invention seen in perspective in FIG. 4). That is, the cage 112 is desirably formed of a resilient biocompatible material such as polypropylene, and axial elongation of the segment 100 is permitted by virtue of the ribs 116 bending to enlarge the axial spaces 120 therebetween”(col. 6, lines 4-14). Thus the reinforcement cage, which is attached to the adapter sleeve, permits the adapter sleeve

Art Unit: 3762

to extend and contract. Therefore, the examiner considers the reinforcement cage to be the “adjustable attachment member configured to attach to the adapter sleeve”.

24. As to claims 15-17, the modified Jassawalla et al. discloses the device substantially as claimed except for the gripping members being gripping pins for engaging with cylindrical ring and spring ring. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the gripping members of Jassawalla et al. to include gripping pins that engagement with cylindrical and spring rings in order to provide the predictable results of ensuring the adapter sleeve and reinforcement cage are sufficiently attached to the sewing ring of the ventricle assist device. Furthermore, such a modification to include pins enables proper positioning of the reinforcement cage on the ventricle assist device.

Art Unit: 3762

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alyssa M Alter/
Examiner
Art Unit 3762

/Niketa I. Patel/
Supervisory Patent Examiner, Art Unit 3762